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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/704,319	11/02/2000	Hiroo Kumagai	1514-00	4918

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IP DEPARTMENT OF PIPER RUDNICK LLP  
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EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/704,319

**Applicant(s)**

KUMAGAI ET AL.

**Examiner**

Robert Landsman

**Art Unit**

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 4, 6 and 12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 is/are allowed.
- 6) ☒ Claim(s) 1, 4, 6 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

The Office Action dated 4/19/04 was made FINAL. However, upon further consideration, new issues have been raised. Therefore, the finality of the rejection of the last Office action has been withdrawn and prosecution on the merits continues.

### ***1. Formal Matters***

- A. Claims 1, 4, 6 and 12 are pending and are the subject of this Office Action.
- B. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

### ***2. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement***

- A. Claims 1, 6 and 12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of a  $\beta$ -endorphin to dynorphin A ratio to diagnose opioid-based pruritis, does not reasonably provide enablement for the use of all kappa and mu opioid peptides to diagnose opioid-based pruritis, nor for certain “diseases” in claim 6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The breadth of the claim is excessive with regard to the scope of claim 1. Applicants are claiming a method of diagnosing opioid-based pruritis using any kappa:mu peptide ratio. However, Applicants have only provided guidance and a working example as to the use of a  $\beta$ -endorphin to dynorphin A ratio. No other guidance or working examples of the use of any other mu and kappa ratios has been provided in the specification. For this reason, it is unpredictable to the artisan what other mu and kappa opioid peptides can be measured to diagnose opioid-based pruritis.

Furthermore, numerous “diseases” in claims 6 and 12 have not been shown to be associated with pruritis – namely lichen, hepatic disease, renal failure, as well as hemodialysis and peritoneal dialysis, which are not diseases.

In summary, the breath is excessive with regard to claiming a method of diagnosing opioid-based pruritis using any kappa:mu peptide ratio. Applicants have only provided guidance and a working example as to the use of a  $\beta$ -endorphin to dynorphin A ratio as well as to a limited number of diseases which are associated with pruritis. Furthermore, it is unpredictable to the artisan what other mu and kappa

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opioid peptides can be used in the claimed method. For these reasons, the Examiner holds that undue experimentation is required to practice the claimed invention.

**3. Claim Rejections - 35 USC § 112, second paragraph**

A. Claims 6 and 12 are rejected under 35 USC 112, second paragraph, since it is not clear that lichen, hepatic disease, renal failure are associated with pruritis. Furthermore, "hemodialysis" and "peritoneal dialysis" are not diseases.

**4. Conclusion**

A. Claim 4 is allowable.

**Advisory information**


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Fax draft or informal communications with the examiner should be directed to (571) 273-0888.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-0700.

Robert Landsman, Ph.D.  
Patent Examiner  
Group 1600  
August 23, 2004

  
ROBERT LANDSMAN  
PATENT EXAMINER